

### Remarks

The Office Action mailed May 5, 2006 has been carefully reviewed and the foregoing amendment has been made in consequence thereof.

Claims 1-48 are now pending in this application. Claims 19-48 are withdrawn from consideration. Claims 1-18 stand rejected.

The rejection of Claim 3 under 35 U.S.C. § 112, second paragraph, as being indefinite, is respectfully traversed. Applicants have amended Claim 3 to address the issue raised by the Examiner in the Office Action. Accordingly, Applicants request that the Section 112 rejection of Claim 3 be withdrawn.

The rejection of Claims 4 and 10 under 35 U.S.C. § 112 for having insufficient antecedent basis, is respectfully traversed. Applicants have amended Claims 4 and 10 to address the issues raised by the Examiner in the Office Action. Accordingly, Applicants request that the Section 112 rejection of Claims 4 and 10 be withdrawn.

The rejection of Claims 1-18 under 35 U.S.C. § 102(b) as being anticipated by Han et al., "Electrospray ionization mass spectroscopic analysis of human erythrocyte plasma membrane phospholipids," Proc. Natl. Acad. Sci., USA, Vol. 91, pp.10635-10639 (1994) (hereinafter referred to as "Han") is respectfully traversed.

Han describes utilizing electrospray ionization mass spectrometry (ESI-MS) for the structural determination and quantitative analysis of specific phospholipid molecular species from subpicomole amounts of human erythrocyte plasma membrane phospholipids. Han further describes quantifying the molecular species determination using a correction factor to compare anionic phospholipids. Specifically, Han describes using a correction factor obtained from a linear regression analysis. (Page 10638, second column) Notably, Han does not describe or suggest a correction factor determined using a least-square regressive non-linear curve fitting. Specifically, as described in paragraph [00127] of the specification, a least-square regressive non-linear curve fitting is required because "there were no differences of sensitivity correction factors between TG regioisomers." As such, the method described in Han is not capable of producing a result as described in the present invention.

Claim 1 recites a method for the determination of triglyceride individual molecular species composition of matter in a biological sample, wherein the method comprises “subjecting the biological sample to lipid extraction to obtain a lipid extract . . . subjecting the lipid extract to two dimensional electrospray ionization tandem mass spectrometry (ESI/MS/MS) . . . determining a sensitivity of the molecular species . . . applying a correction factor to the sensitivity to produce the determination, wherein the correction factor is determined using a least-square regressive non-linear curve fitting.”

Han does not describe nor suggest a method for the determination of triglyceride individual molecular species composition of matter in a biological sample, as is recited in Claim 1. More specifically, Han does not describe nor suggest a method including applying a correction factor to a sensitivity to produce a determination, wherein the correction factor is determined using a least-square regressive non-linear curve fitting, as required by Applicants’ claimed invention. Rather, in contrast to the present invention, Han describes quantifying a molecular species determination using a correction factor that is derived from a linear regression analysis. Notably, the use of a linear regression analysis, as described by Han, does not account for a lack of differences in sensitivity correction factors between TG regioisomers. As such, the method described by Han does not produce the determination described by Claim 1.

Accordingly, for at least the reasons set forth above, Claim 1 is submitted to be patentable over Han.

Claims 2-7 depend from independent Claim 1. When the recitations of Claims 2-7 are considered in combination with the recitations of independent Claim 1, Applicants submit that dependent Claims 2-7 likewise are patentable over Han.

Claim 8 recites a method for the determination of triglyceride individual molecular species composition of matter directly from a lipid extract of a biological sample, wherein the method comprises “subjecting said lipid extract to electrospray ionization tandem mass spectrometry (ESI/MS/MS) . . . determining a sensitivity of the molecular species . . . applying a correction factor to the sensitivity to produce the determination, wherein the correction factor is determined using a least-square regressive non-linear curve fitting.”

Han does not describe nor suggest a method for the determination of triglyceride individual molecular species composition of matter directly from a lipid extract of a biological sample, as is recited in Claim 8. More specifically, Han does not describe nor suggest a method including applying a correction factor to a sensitivity to produce a determination, wherein the correction factor is determined using a least-square regressive non-linear curve fitting, as required by Applicants' claimed invention. Rather, in contrast to the present invention, Han describes quantifying a molecular species determination using a correction factor that is derived from a linear regression analysis. Notably, the use of a linear regression analysis, as described by Han, does not account for a lack of differences in sensitivity correction factors between TG regioisomers. As such, the method described by Han does not produce the determination described by Claim 8.

Accordingly, for at least the reasons set forth above, Claim 8 is submitted to be patentable over Han.

Claims 9-17 depend from independent Claim 8. When the recitations of Claims 9-17 are considered in combination with the recitations of independent Claim 8, Applicants submit that dependent Claims 9-17 likewise are patentable over Han.

Claim 18 recites a diagnostic kit for the determination of triglyceride molecular species in a biological sample comprising components suitable for carrying out a method including "subjecting the biological sample to lipid extraction to obtain a lipid extract . . . subjecting the lipid extract to two dimensional electrospray ionization tandem mass spectrometry (ESI/MS/MS) . . . determining a sensitivity of the molecular species . . . applying a correction factor to the sensitivity to produce the determination, wherein the correction factor is determined using a least-square regressive non-linear curve fitting."

Han does not describe nor suggest a diagnostic kit, as is recited in Claim 18. More specifically, Han does not describe nor suggest a diagnostic kit suitable for carrying out a method including applying a correction factor to a sensitivity to produce a determination, wherein the correction factor is determined using a least-square regressive non-linear curve fitting, as required by Applicants' claimed invention. Rather, in contrast to the present invention, Han describes quantifying a molecular species determination using a correction factor that is derived from a linear regression analysis. Notably, the use of a linear regression analysis, as described by Han, does not account for a lack of differences in sensitivity

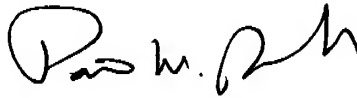
correction factors between TG regioisomers. As such, the method described by Han does not produce the determination described by Claim 18.

Accordingly, for at least the reasons set forth above, Claim 18 is submitted to be patentable over Han.

For the reasons set forth above, Applicants respectfully request that the Section 102(b) rejection of Claims 1-18 be withdrawn.

In view of the foregoing amendments and remarks, all the claims now active in this application are believed to be in condition for allowance. Reconsideration and favorable action is respectfully solicited.

Respectfully Submitted,



---

Patrick Rasche  
Registration No. 37,916  
ARMSTRONG TEASDALE LLP  
One Metropolitan Square, Suite 2600  
St. Louis, Missouri 63102-2740  
(314) 621-5070